IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	
Plaintiff,	)	
v.	)	**Case No. 3:05-0444**
	)	**Judge Trauger**
PFIZER INC., *et al.*,	)	
Defendants.	)	

MEMORANDUM

Pending before the court are the objections to expert witness statements filed by the plaintiff and defendants (Docket Nos. 225, 228-32). These objections will be granted and denied as described below.

As an initial matter, both parties make a number of objections pursuant to Federal Rule of Evidence 702, arguing that particular testimony is not supported by a reliable scientific methodology or is otherwise improper. Generally speaking, these objections will be denied. If the parties wished to exclude testimony on this basis, the proper procedure was to file a *Daubert* motion sometime before the eve of trial. Specifically, motions *in limine* were due by April 16, 2010, (Docket No. 38 at 2), and the parties had ample information on which to base motions of this sort by that deadline.

Similarly, the plaintiff objects that several of the defendants' experts are inappropriately testifying regarding general causation, arguing that this violates a scheduling order by the MDL

court regarding expert disclosure. But the proper time to raise this issue was when the plaintiff receive those experts' reports, or, at the latest, by the time motions *in limine* were due. Unless an expert's testimony exceeds the scope of that expert's report – which only a few of the objections indicate – the court will not exclude the testimony on these grounds.[1]

I. The Plaintiff's Objections to the Defendants' Expert Witness Statements

The plaintiff makes two general objections to the defendants' experts: (1) the statements are unduly duplicative because three experts are testifying regarding specific causation; and (2) the statements contain anecdotal evidence based on the expert's experience with Neurontin.

As to the first objection, it is possible that the testimony by the defendants' experts will become unduly cumulative. For example, the defendants have offered two psychiatrists and one neurologist who will testify that Smith committed suicide because he was depressed and in pain, not because he took Neurontin. The court will rule at trial as to whether any of this testimony is cumulative, as that will depend, to some extent, on factors such as whether experts who have already testified were impeached on cross examination. As to the second objection, the court will generally allow experts to testify regarding how their own clinical experience informs their opinions. *See Cantrell v. GAF Corp.*, 999 F.2d 1007, 1014 (6th Cir. 1993) ("Nothing in Rules 702 and 703 or in *Daubert* prohibits an expert witness from testifying to confirmatory data, gained through his own clinical experience . . . .").

A. Peter Donofrio, M.D.

[1] Of course, these issues will be preserved for appeal.

The defendants have offered Donofrio, who is a neurologist, to testify that: (1) Neurontin is safe and effective for treating neuropathic pain and is regarded as a useful treatment option; (2) Neurontin's safety labeling was sufficient; (3) Smith's Neurontin dosage was relatively low and was insufficient to provide pain relief; and (4) Smith's suicide was caused by his chronic pain and depression, not by Neurontin.

The plaintiff objects under Rule 702 to Donofrio's opinion that Neurontin is "safe and effective," arguing that this is a legal term used by the FDA in the drug-approval process and that such testimony is duplicative of other experts' testimony. It is unclear why the plaintiff did not raise this issue in a motion *in limine*. Nevertheless, aside from whether "safe and effective" is a legal term of art, the court agrees that Donofrio's lengthy testimony regarding Neurontin's general safety is unduly cumulative of the testimony of the defendants' other experts. Numerous other experts will analyze studies of Neurontin's safety and opine on whether the drug can or cannot cause suicidality. Similarly, other experts will testify regarding the adequacy of Pfizer's safety labeling. There is simply no need for Donofrio to give cumulative testimony on these matters. The plaintiff further objects that other aspects of Donofrio's testimony are duplicative; the court will reserve judgment on these objections until trial.

Donofrio will be allowed, however, to testify regarding the effectiveness of Neurontin in treating neuropathic pain. Donofrio's testimony regarding the standard of care in treating such pain is both probative and admissible. This includes testimony regarding: (1) whether Neurontin is a common treatment for neuropathic pain; (2) whether Neurontin is effective in treating such pain; (3) Donofrio's clinical experience regarding effective Neurontin dosages; and (4) whether

Smith's dosage was sufficient to treat his neuropathic pain.

The plaintiff objects to Donofrio's reference to a statement of Smith's daughter contained in the police report prepared after Smith's death. She stated that, shortly before Smith started taking Neurontin, he had told her that he "wish[ed] he could die because of pain and depression." (Docket No. 173, Ex. 1 at 12.) The defendants do not dispute that the daughter's statement is hearsay, but they point to Rule 703, which allows experts to base their opinions on inadmissible evidence if the evidence is "of a type reasonably relied upon by experts in the particular field." Fed. R. Evid. 703. The rule further provides: "Facts or data that are otherwise inadmissible shall not be disclosed to the jury by the proponent of the opinion or inference unless the court determines that their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect." Although the statement may aid the jury in assessing Donofrio's opinion, it also has the potential to be unduly prejudicial, even if the court gives a limiting instruction. Because this statement may otherwise come into evidence before Donofrio's testimony, the court will defer ruling on this objection at this time.

The plaintiff also attacks statements about Donofrio's anecdotal experiences. Much of the expert testimony in this case involves analysis of clinical studies and medical literature. The court agrees with the plaintiff that, compared to such analysis, the fact that "[n]o patient has ever reported suicidality to [Donofrio] in connection with his or her Neurontin use," (Docket No. 173, Ex. 1 at 8), is much less probative of Neurontin's tendency to increase the risk of suicide. It would be improper for the jury to rely on this evidence to assess general causation, because the number of Donofrio's patients is, relatively speaking, insignificant. Because this kind of

anecdotal evidence might unduly prejudice the jury, the court will exclude this comment.

Finally, the court will exclude Donofrio's reference to the fact that some European countries have approved Neurontin for treatment of general neuropathic pain. This is tangential to the central issues of this litigation, and without testimony regarding the standards employed by those European regulatory agencies, which is not proposed to be offered, the potential for prejudice outweighs the probative value of the statement.

B. Douglas Jacobs, M.D.

The defendants have offered Jacobs, who is a psychiatrist, to testify that: (1) The FDA's meta-analysis and other studies do not show that Neurontin increases the risk of suicide; and (2) Smith committed suicide because of his chronic pain, not because of Neurontin.

The plaintiff objects to portions of Jacobs' testimony regarding the FDA meta-analysis and general causation, arguing that the statements are outside the scope of Jacobs' expert report. The defendants do not dispute that one statement is outside the scope, so the court will grant that objection. It appears that the other statements involve studies that were discussed in Jacobs' reports, however, so the court will deny those objections.

The plaintiff also objects to Jacobs' criticism of a "psychological autopsy form" that plaintiff's expert Maris used to gather relevant information for his report. According to the defendants, the form, which Maris has used in other cases, "seeks biographical, health, familial, and other information about Mr. Smith." (Docket No. 241 at 24.) Jacobs will testify that a legal assistant to the plaintiff's counsel filled out the form and that the form contained certain inaccuracies and omissions. The plaintiff argues that the parties agreed that "[d]rafts of expert

reports . . . should not be questioned by the parties" and that the testimony should be excluded because the form "was a subject precluded from questioning and discovery." (Docket No. 225 at 10.) The form is not a "draft" of Maris' expert report, and Maris was questioned about the form at his deposition. Jacobs received a copy of the form. Clearly, the form was not shielded from discovery. However, Jacobs testifying as to who filled out the form is inadmissible hearsay. Depending upon Maris' testimony as to his reliance on the information entered on the form in fashioning his opinions, the accuracy of the information on the form might or might not be relevant for impeachment purposes. The court will reserve a ruling on the plaintiff's objection.

C. Charles Taylor, Ph.D.

The defendants have offered Taylor, who is a neuroscientist, to testify regarding Neurontin's effects on patients' brain chemistry. The plaintiff has objected pursuant to Rule 702 to two statements regarding an experiment on brain tissue, arguing that the testimony is outside the witness' expertise. First, it is unclear how this is outside Taylor's expertise. Second, this content was presumably included in Taylor's expert report. Because the plaintiff did not raise these issues in a *Daubert* motion, the court will not address them now.

D. Robert Granacher, M.D.

The defendants have offered Granacher, a psychiatrist, to testify that: (1) Smith's hopelessness and suicide were caused not by Neurontin, but by his pain and lack of available treatment options; and (2) Smith had risk factors for suicide that were not increased by his use of Neurontin.

The plaintiff again makes multiple objections under Rule 702 and on the grounds that

Granacher's testimony is unduly cumulative. The Rule 702 objections will be denied, and a ruling on the objections regarding cumulativeness will be deferred, for the reasons mentioned above. As with the plaintiff's objections to Donofrio's testimony, the court will defer ruling on the hearsay objection to Smith's daughter's statement to the police.

The plaintiff also objects to Granacher's testimony regarding his previous treatment of priests, ministers, and seminary professors, and how people in those professions tend to deal with depression. The court will allow Granacher to explain how his clinical experience informs his assessment of Smith's actions. The court does agree, however, that Granacher's statement, "I have never seen anything in my own patients that even hinted that a patient developed depression or suicidal thoughts because of treatment with Neurontin," is inadmissible. In light of the extensive testimony regarding clinical studies, the possibility of prejudice outweighs the probative value of this anecdotal evidence.

E. Henry Grabowski, Ph.D.

The defendants have offered Grabowski, an economist, to rebut the testimony of plaintiff's expert Charles King. Grabowski will testify that: (1) King has no basis to conclude that off-label marketing of Neurontin influenced all doctors; (2) King has not proven that any specific prescription was caused by marketing; (3) King has not analyzed this particular case; and (4) King's opinions are flawed and unsupported.

The plaintiff spends several pages arguing that Grabowski's testimony should be excluded because his report and testimony are directed solely at the validity of King's opinions. First, this is essentially a motion *in limine* to exclude Grabowski's testimony, which should have

been filed by April 16. Second, the plaintiff cites no authority for the proposition that an expert cannot be offered to rebut an opposing expert's methodology. Indeed, it is standard for an expert witness to point out methodological flaws in an opposing expert's analysis. Essentially all of the plaintiff's objections to Grabowski's testimony argue that Grabowski's attacks on King's methodology are "argumentative" and improper under Rule 702. These contentions are meritless.

F. Janet Arrowsmith, M.D.

The defendants have offered Arrowsmith, an epidemiologist, to testify that: (1) Neurontin's safety labeling was adequate; (2) the package insert contained information concerning suicidal behavior reported during clinical testing; and (3) there was no reason for Pfizer to warn of suicidal behavior before 2009 because the available information did not establish that Neurontin increased the risk of suicidal behavior.

The plaintiff repeatedly objects that Arrowsmith's testimony is duplicative of defense expert Ruggieri's testimony. As already explained, the court will reserve judgment on this issue until trial. The court will also deny the plaintiff's objections under Rule 702 regarding lack of foundation and lack of reliable methodology.

The plaintiff objects to the following statement as misleading and prejudicial: "Had FDA reviewers concluded that Neurontin increased the risk of depression or suicide, they would have been obligated to have required a warning in the label at the time the drug was approved." (Docket No. 225 at 27.) The plaintiff also objects to other statements as misleading or speculative. For example, the plaintiff points out that Arrowsmith's conclusions regarding FDA

reviewer Cynthia McCormick's work are contradicted by a quote from McCormick in a document. There are also several occasions where Arrowsmith allegedly makes incorrect references to the opinions of the plaintiff's expert Blume. The court will not exclude these statements, as they are proper fodder for cross-examination of the witness. As for Arrowsmith's supposed speculation, she is allowed to review the relevant documents, interpret them, and draw conclusions. The court does not find that Arrowsmith's testimony contains impermissible speculation.

Finally, the plaintiff objects that Arrowsmith lacks the expertise to testify regarding advertising. This is another argument that should have been raised in a *Daubert* motion.

G. Robert Gibbons, Ph.D.

The defendants have offered Gibbons, a biostatistician and epidemiologist, to testify that: (1) various studies, including the FDA's meta-analysis, do not show that Neurontin causes suicide or suicidal behavior; and (2) there is no statistical basis to require a suicide warning for Neurontin.

For the reasons mentioned above, the court will deny the plaintiff's objections to Gibbons' methodology and experience. The plaintiff argues that Gibbons impermissibly speculates when he concludes that, if the FDA had removed two particular drugs from its meta-analysis, the FDA would not have issued an Alert or a new product warning. (Docket No. 225 at 39.) But this naturally follows from Gibbons' conclusion that the FDA would have found no increase in suicide risk.

Finally, the plaintiff argues that Gibbons' deposition testimony contradicts his conclusion

that anti-epileptic drugs "may . . . reduce[] risk for suicide attempt" in certain patients. Again, the plaintiff may cross-examine Gibbons on this matter. The court will defer ruling on the plaintiff's cumulativeness objections. The remainder of the plaintiff's objections are meritless.

H. Alex Ruggieri, M.D.

The defendants have offered Ruggieri, a physician, to testify that: (1) Pfizer acted reasonably and complied with regulatory requirements in monitoring Neurontin's safety; (2) the information available to Pfizer did not show that Neurontin increased the risk of suicide; (3) no signal emerged to raise safety concerns in the off-label use of Neurontin; and (4) Pfizer's safety labeling was sufficient.

The plaintiff argues that Ruggieri's statement simply recounts pages upon pages of facts, without applying any expertise. She argues that an expert may not "'simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring the litigant.'" (Docket No. 225 at 48 (quoting *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008)).) First, this is another Rule 702 argument that should have been raised, based on Ruggieri's report, at the motion *in limine* stage. Second, the so-called narrative passages highlighted by the plaintiff explain to the jury the facts that underlie Ruggieri's expert conclusions. For example, Ruggieri's discussion on pages 8-14 of his statement describes the information that he reviewed in reaching his opinion that the postmarketing data through 2002 showed no evidence of any safety signal. Without this information, Ruggieri's conclusions would lack context, especially in a case that is as complex as this one. The court will also deny the plaintiff's objections that Ruggieri's testimony lacks a foundation and defer ruling on the

objections that his testimony is cumulative.

The plaintiff also objects to Ruggieri's reliance on an email that was allegedly sent from an FDA official, Donald Dobbs, to Ruggieri. The email stated that the FDA does not believe that adverse event reports "can be interpreted properly in this situation" and instead believes that "the only way to establish whether or not the drugs are responsible for suicidality is to analyze controlled trial data." (Docket No. 225 at 50.) The plaintiff objects that this document is unauthenticated, noting that it lacks any email routing information and fails to include Dobbs' contact information. (*Id.*) But a document can also be authenticated by "[t]estimony that a matter is what it is claimed to be." Fed. R. Evid. 901(b)(1). Ruggieri's own testimony that the email was sent from the FDA will authenticate the document.

However, the plaintiff further contends that Dobbs' statements are hearsay. The court agrees that the statements are being offered for the truth of the matter asserted; Ruggieri will testify that "[t]he FDA's repeated statements regarding the unreliable and un-interpretable nature of postmarketing data are contrary to the assertions made by the plaintiff's experts, who use postmarket adverse event report data . . . as a basis to [link] Neurontin and suicidality." (Docket No. 178, Ex. 1 at 21.) The court rejects the defendants' argument that the statements fall under the hearsay exception in Rule 803(8), which allows admission of "statements . . ., in any form, of public offices or agencies, setting forth . . . the activities of the office or agency." Fed. R. Evid. 803(8)(A). The email reflects the opinion of a single FDA official, and the statements are not a record of "activities" undertaken by the FDA. Nor is the court persuaded that the email should

be admitted under Rule 703. Accordingly, the court will grant the plaintiff's objection.[2]

I. Sheila Weiss Smith, Ph.D.

The defendants offer Weiss Smith, an epidemiologist, to testify that: (1) adverse event reports cannot establish that Neurontin causes suicide; (2) the FDA's adverse event database does not support the finding that a signal for suicide existed; (3) the methodology used by plaintiff's expert Blume to analyze the database is flawed; and (4) information in the database is unreliable and uninterpretable.

The plaintiff objects that Weiss Smith's fourth opinion, that adverse event data is uninterpretable, was not disclosed in accordance with Federal Rule of Civil Procedure 26. The defendants point out that Weiss Smith's initial report stated that "direct-to-FDA reports produce[] a significant reporting bias in the adverse event database, such that one would not reach any reliable conclusion regarding a signal." (Docket No. 91, Ex. 1 at 14.) But this statement referred only to the increase in reports after law firms began submitting Neurontin-related adverse event reports. The defendants also argue that pages 27-31 of Weiss Smith's supplemental report discussed the limitations of the adverse event database. Although that section did discuss flaws in the plaintiff's experts' analysis of the database, it did not conclude that adverse event reports, in general, are unreliable and uninterpretable. Accordingly, she cannot now testify to that opinion. *See* Fed. R. Civ. P. 26(a)(2)(B)(i).

Weiss Smith makes several references to the fact that there was an increase in adverse

[2] Defense expert Arrowsmith also discusses this email. Her testimony on the subject will be excluded.

event report filings in 2005 after the plaintiff's lawyers began advertising regarding Neurontin. In addition, some of Weiss Smith's charts are shaded "to show when the adverse event data base was corrupted by attorney advertising and publicity surrounding the litigation." (Docket No. 181, Ex. 1 at 13.) The plaintiff objects to these references as being unduly prejudicial. The court agrees. As discussed at the pre-trial conference, the plaintiff does not rely on adverse event reports after the second half of 2003, so an influx of reports that occurred in 2005 is irrelevant. Any reference to the plaintiff's counsel advertising will only serve to prejudice the jury.

The majority of the plaintiff's other objections rest on Rule 702 grounds. The court will deny these for the reasons listed above.

II. The Defendants' Objections to the Plaintiff's Experts

A. Ronald Maris, Ph.D.

The plaintiff has offered Maris, a psychiatry professor, to testify that: (1) suicide has many factors; (2) Neurontin is a mood-altering drug that can cause suicide; (3) Smith was at a low risk for suicide and began having mood changes after taking Neurontin; (4) Smith did not kill himself because of chronic pain; and (5) Neurontin was a substantial contributing factor to Smith's suicide.

The defendants object to Maris' introductory remarks, in which he clarifies that he is distantly related to the baseball player Roger Maris. These are clearly irrelevant, and the court will exclude this testimony.

The defendants object to Maris' opinion and brief testimony that "many prescription drugs can cause suicides." (Docket No. 180, Ex. 9 at 3.) But defense expert Jacobs is testifying

that no textbook, literature, clinical study, or FDA analysis "on the relationship between drugs and suicidality lists medication as a cause of suicide." (Docket No. 177, Ex. 1 at 5.) Maris is entitled to rebut this claim. The court will also allow Maris to disclose that he has previously testified for plaintiffs in cases alleging that medication caused a suicide.

The defendants also object to Maris' opinion that Smith was taking Neurontin at the time of his death. Maris simply recounts the evidence on the subject, which mostly consists of Smith's statements to his family members and doctors. Maris does not apply any particular expertise to the facts. Indeed, determining whether Smith was actually taking his medication does not require "scientific, technical, or other specialized knowledge," Fed. R. Evid. 702, and is completely within the province of a lay jury.[3] Accordingly, expert testimony on the subject is not helpful and will be excluded.

The defendants object to a footnote in Maris' statement stating that, for liability, "[a]ll that is required is that Neurontin was one of the causes of Richard Smith's suicide, not the only cause. It was a necessary, but not sufficient condition for his suicide." This testimony will be excluded. It is the job of the court, not an expert witness, to instruct the jury regarding the applicable law.

The court will deny the defendants' other objections based on Rule 702. Many of these

[3] The plaintiff responds that the defendants' experts do the same thing. This is true. (*See, e.g.*, Docket No. 173, Ex. 1 at 14-15 (Donofrio testimony involving simple math to determine the number of pills Smith would have taken, had he been taking Neurontin as prescribed, and comparing that to the number of pills left in Smith's medicine bottle after his suicide).) But this does not make Maris' testimony admissible. Rather, it is an inappropriate topic for experts from both sides. Of course, the experts may testify that their opinions are based on certain *assumptions* as to what dosage Smith was taking.

issues were already ruled on by the MDL court at the *Daubert* stage. The court will also deny objections regarding introduction of the new warning label required by the FDA. The court has already ruled that such evidence is admissible. (Docket No. 199 at 5-7.) The defendants object that scientific studies and academic literature quoted by Maris are hearsay, but the court will allow this evidence under Rule 703, because it will assist the jury in evaluating Maris' opinion.

B. Sander Greenland, Ph.D.

The plaintiff has offered Greenland, an epidemiologist, to testify that: (1) certain data from Pfizer does not show that Neurontin does not cause suicidal behavior; (2) the FDA's meta-analysis was correct and is supported by subsequent reports; and (3) defense expert Gibbons' opinions are flawed.

The defendants' objections to Greenland's testimony are exclusively based on Rules 702 and 403. These objections will be denied. The defendants were free to raises issues regarding Greenland's methodology at the motion *in limine* stage. If they feel that any of Greenland's testimony is misleading, they can cross examine him on those points.

C. Michael Trimble, M.D.

The plaintiff has offered Trimble, a medical doctor and professor emeritus of neurology, to testify that: (1) Neurontin reduces serotonin levels and increases GABA levels in the brain; (2) Neurontin can cause depression and suicidality; and (3) Neurontin was a cause of Smith's suicide.

The defendants object to Trimble's references to, and quotations from, (1) excerpts from a Pfizer website, (2) deposition testimony of a Pfizer employee, and (3) certain academic articles

published in 2000, 2006, and 2008. The defendants argue that Trimble did not mention these items in his expert reports. Federal Rule of Civil Procedure 26(a)(2)(B) requires an expert's report to contain "the data or other information considered by the witness in forming [his opinions]," as well as "any exhibits that will be used to summarize or support them." Fed. R. Civ. P. 26(a)(2)(B)(ii)-(iii).

The plaintiff, citing *Thompson v. Doane Pet Care Co.*, 470 F.3d 1201 (6th Cir. 2006), argues that experts are "not bound by the four corners" of their expert reports. In *Thompson*, an accounting expert was barred by the lower court from testifying that his opinion was based on generally accepted accounting principles (GAAP) because the expert report did not specifically refer to GAAP. The Sixth Circuit reversed, noting that Rule "26(a)(2)(B) does not limit an expert's testimony simply to reading his report" and instead "contemplates that the expert will supplement, elaborate upon, explain and subject himself to cross-examination upon his report." *Id.* at 1203. But this decision was based largely on the fact that, "[i]n the absence of an alternative accounting convention pertinent to the case, it may be assumed that certified public accountants base their calculations and opinions on the normal general standards of their profession." *Id.*

Thompson is inapposite here. Trimble's testimony is not invoking the common background principles of his field. Instead, he is commenting on specific exhibits and articles that were not previously disclosed in his reports. If Trimble has never previously referred to an exhibit or document, he is now barred from testifying regarding that item.

The plaintiff responds that the web site excerpt is contained in her general exhibit list and

that the deposition testimony has been designated for trial. But, as mentioned above, Rule 26 requires an expert's report to disclose the materials he is using in support of his opinions. Parties cannot simply have their experts discuss anything that has been designated as a trial exhibit. The plaintiff also argues that several of the articles at issue were mentioned in two supplemental disclosures filed in April 2010 in the MDL court. She does not, however, provide a specific citation for these documents, and the court is unable to locate any such disclosures in the docket of D. Mass. Case No. 04-10981. Regardless, the plaintiff does not explain why she only filed disclosures one month ago when the articles were published in 2000, 2006, and 2008.[4]

Finally, one of the articles in dispute was covered in Trimble's testimony during the *Daubert* stage. For that item, the defendant cannot claim lack of notice, so the court will deny that objection. The court will also deny the defendants' Rule 702 objection to Trimble's testimony regarding specific causation.

D. Charles King III, Ph.D.

The plaintiff has offered King, an economist, to testify that: (1) marketing efforts contributed significantly to off-label sales of Neurontin; (2) significant off-label sales would have continued, had Pfizer discontinued off-label promotion; (3) Pfizer's off-label marketing directly or indirectly influenced all or substantially all doctors prescribing Neurontin; and (4)

[4] The plaintiff points out that Trimble is using one of the articles, which involves Neurontin's effect on the human brain, to rebut the defendants' argument that the plaintiff is relying on animal studies. (Docket No. 237 at 5.) But Rule 26 provides that expert evidence that is "intended solely to contradict or rebut evidence on the same subject matter identified by [an opposing expert]" must be disclosed "within 30 days after the other party's disclosure." Fed. R. Civ. P. 26(a)(2)(C)(ii).

suppression of information regarding serious adverse events enabled the growth of Neurontin's off-label sales.

The defendants object that a recent study cited by King was not disclosed in his expert report, but the plaintiff responds that it was disclosed on April 12, "as soon as the study was published and made known to the expert." (Docket No. 238 at 2.) The defendants' objection does not indicate that they did not receive this disclosure. The defendants previously filed a motion *in limine* to exclude two later-disclosed studies relied on by the plaintiff's other experts, (Docket No. 112), and the parties and the court discussed the issue at length in the pre-trial conference. (Docket No. 214 at 38-46.) If the defendants also wished to exclude this third study, they should have raised the issue at that time.

The court will also deny any objection by the defendants under Rule 702 or 703 that does not indicate that King's testimony is outside the scope of his report. The court previously denied the defendants' motion *in limine* to exclude King's testimony. (Docket No. 191 at 15-20.) For example, King opines that Pfizer suppressed information about adverse effects. The defendants repeatedly object that he is not qualified to make determinations regarding the "adverse effects" of Neurontin. But King does not engage in any medical analysis – rather, he relies on statements contained in the defendants' documents regarding whether certain studies were delayed or suppressed. This is permissible.

King will testify that Warner-Lambert advertised off-label uses of Neurontin at continuing education events, and an exhibit to his testimony highlights a quote from a sales document: "Medical education drives this market!" The defendants request a limiting instruction

that the sponsorship of continuing medical education events by drug companies is not considered promotion because it falls under a "safe harbor" regulation. But the plaintiff points out that the defendants admitted in their guilty plea that sponsorship of such events for off-label promotion was illegal (and, therefore, could not have been within the safe harbor). Accordingly, the court will deny the objection.

King's statement features some discussion of the defendants' efforts to market Neurontin for off-label uses other than the treatment of neuropathic pain. The defendants object that this is irrelevant. The court disagrees; this evidence is relevant to show the general effectiveness of off-label marketing campaigns. The court will deny the rest of the defendants' relevance objections.

E. Cheryl Blume, Ph.D.

The plaintiff has offered Blume, who has a Ph.D. in pharmacology and has experience with FDA drug submissions, to testify regarding FDA regulations and opine that: (1) Neurontin increases the risk of suicide; (2) Pfizer ignored red flags regarding suicidality; and (3) Pfizer failed to warn of this danger.

The defendants list several overarching objections to Blume's testimony. First, the defendants claim that Blume should be prevented from testifying that the defendants failed to warn "doctors and patients," as opposed to simply "doctors," of Neurontin's dangers. They argue that, because Tennessee has adopted the "learned intermediary" doctrine, *see Pittman v. Upjohn Co.*, 890 S.W.2d 425 (Tenn. 1994), warnings to patients are irrelevant. The court disagrees that Blume's phrasing is unduly prejudicial or misleading. It is true that a pharmaceutical company is generally relieved from liability if they properly warn a patient's

doctor of a particular side effect.[5] But the point of warning doctors is, ultimately, to protect patients. It is unremarkable that the purpose of issuing product warnings is to protect both doctors and patients. Indeed, the MDL court previously held that "a manufacturer of a pharmaceutical has a duty to disclose to *physicians and patients* material facts about the risks of the drug." *In re Neurontin Mktg.*, 618 F. Supp. 2d 96, 110 (D. Mass 2009) (emphasis added). The court will deny this objection.

Second, the defendants argue that Blume improperly summarizes documents and offers "spin" without applying any expertise. (Docket No. 232 at 3-6 (citing *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950 (D. Minn. 2009); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531 (S.D.N.Y. 2004); *In re Prempro*, 554 F. Supp. 2d 871).) This is essentially the same objection that the plaintiff raised to the testimony of defense expert Ruggieri, and the court will deny the defendants' objection for the same reasons. The defendants should have raised this objection earlier, rather than on the eve of trial. Indeed, in *In re Viagra*, the court was ruling on a motion to exclude at the summary judgment stage, and in *In re Rezulin*, the court was ruling on a motion *in limine*. Also, the court finds that Blume's discussion of the record gives context to her conclusions, which is necessary in a complex case. The defendants further argue that Blume improperly offers her personal views on the defendants' conduct, (Docket No. 232 at 6-8), but the court finds that this objection is meritless.

Third, the defendants object to Blume's testimony regarding the defendants' failure to

[5] The plaintiff points out that there are exceptions to this general rule, (Docket No. 224 at 3-4), but none seem to apply here.

test Neurontin's safety for off-label purposes, arguing that nothing supports the premise that any particular subgroup of off-label patients faced a higher risk from Neurontin. (Docket No. 232 at 8-10.) This is a Rule 702 and 703 objection that was more properly made at the motion *in limine* stage. The defendant is free to cross-examine Blume on this topic.

Fourth, the defendants argue that Blume's testimony regarding the "Gabapentin Data Capture Aid" is inadmissable under Rule 407 because it is a subsequent remedial measure. The capture aid is a safety monitoring system developed by the defendants in 2006. Blume seeks to testify that:

> The Defendants . . . did implement a system for collecting information about suicidal behavior, but only after Mr. Smith died. There is no reason that this could not have been done long before his death. Essentially, Defendants did too little, too late. . . .
>
> [T]he Defendants should have and could have come up with this plan, years before Mr. Smith died. This exhibit is important because it shows the Defendants knew it was feasible to look specifically at suicide related events. There is no reason why this plan was delayed until 2006. It should have been implemented in 1994 when the drug was first put on the market and Defendants already knew that there were concerns with depression and suicide attempts with Neurontin.

(Docket No. 180, Ex. 4 at 3-4, 10.)

Rule 407 prohibits evidence of subsequent remedial measures. It states:

> When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of

precautionary measures, if controverted, or impeachment.

Fed. R. Evid. 407.

The Data Capture Aid falls squarely within the protection of Rule 407. The plaintiff argues that Blume mentions the Aid simply to show that it was "feasible" for the defendants to implement such a system. But feasibility evidence is only admissible if the opposing party "controvert[s]" feasibility. *Id.* As the defendants argue, they "have never contended that such a plan was not feasible, only that it was not necessary at the time of Mr. Smith's death to evaluate the safety of Neurontin." (Docket No. 232 at 10.) The court will exclude references to the Gabapentin Data Capture Aid.

Fifth, the defendants argue that Blume is unqualified to offer opinions about Neurontin's "mechanism of action," or how it affects brain chemistry. (Docket No. 232 at 11-12.) The MDL court previously rejected this argument, and the court will not now revisit the issue. *See In re Neurontin Mktg.*, 612 F. Supp. 2d 116, 158 (D. Mass. 2009) (rejecting argument that "Dr. Blume is not qualified to testify about Neurontin's mechanism of action or any medical theory of causation").

Sixth, the defendants argue that Blume improperly seeks to show a chart regarding "proportional reporting ratio," or "PRR," that was assembled by the plaintiff's counsel. (Docket No. 12-14.) At her deposition, Blume testified that she did not "audit or in any way validate" this work product. (Docket No. 232, Ex. 2 at 92, 97-98.) She specifically agreed that she did not "do any independent work to validate the graph" listed at paragraph 39 of her witness statement. (*Id.* at 102-03.) She also testified that she was "not capable of validating the [plaintiff's

lawyer's] work." (*Id.* at 69.)

The plaintiff claims that the MDL court rejected this argument, but they give no citation to the record in support. The plaintiff also argues that this court's decision on the motion *in limine* to exclude the testimony of plaintiff's expert King is on point here. There, the court held:

> The defendants also argue that the plaintiff's attorneys exercised too much influence over King, largely because the charts in King's report were created by an outside firm hired by the attorneys. (Docket No. 119 at 9-10.) But nothing indicates that King did not adequately review or verify this work. *See In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 963 (D. Minn. 2009) (refusing to exclude expert testimony, even though a chart was prepared by plaintiff's counsel, because the expert reviewed "voluminous materials prior to reaching her conclusion" and because there was no indication that the chart "was incapable of verification or meaningful review").

(Docket No. 191 at 19.) But here, Blume has admitted that she had not verified the work and is incapable of verifying the work. The court will exclude Blume's discussion of this chart.[6] *See Ellipsis, Inc. v. Color Works, Inc.*, 428 F. Supp. 2d 752, 761 (W.D. Tenn. 2006) (excluding testimony partly because the expert "relied exclusively on data provided by [the plaintiff]" and "failed to verify the information"); *SMS Sys. Maintenance Servs. v. Digital Equip. Corp.*, 188 F.3d 11, 25 (1st Cir. 1999) ("[A]n expert must vouchsafe the reliability of the data on which he relies and explain how the cumulation of that data was consistent with standards of the expert's

[6] The defendants reference two other charts created by the plaintiff's counsel and argue that they should be excluded because they were not disclosed in her report. (Docket No. 232 at 13-14.) The defendants do not argue that Blume did not properly verify the information in these charts. (*See id.*) But the plaintiff states that these exhibits "were prepared in response to Defendants' challenge to Dr. Blume's testimony on general causation" and that Blume submitted a declaration that referenced the declaration containing the charts. (Docket No. 244 at 11-12.) Accordingly, the court will not exclude these charts.

profession.").

In sum, the court will exclude Blume's testimony regarding the Gabapentin Data Capture Aid, (Docket No. 180, Ex. 4 ¶¶ 15, 37), and the PRR chart. (*Id.* ¶¶ 38-41).

The defendants make a number of other objections, which the court will rule on in accordance with its decisions above. The court will deny the remainder of the defendants' objections, except that the court will: (1) exclude the statement in paragraph 13 ("Mr. Smith is the victim of the Defendants' actions") as being unduly prejudicial; (2) exclude the statement in paragraph 14 ("Pfizer wasn't careful and people like Mr. Smith died") as being unduly prejudicial; (3) exclude the statement in paragraph 23 ("Otherwise it was 'don't ask, don't tell' and business as usual") as being unduly prejudicial; exclude the statement in paragraph 42 ("Unfortunately for Mr. Smith, the company only did this because FDA required the company to review the information") as being unduly prejudicial and being improper state-of-mind testimony; (4) exclude the testimony in paragraphs 43-45 because the plaintiff does not dispute that the opinion was not previously disclosed; and (5) exclude the statement in paragraph 48 ("So, don't believe the defendants if they claim that they ever warned for 'suicide' during Mr. Smith's life") as being unduly prejudicial.

CONCLUSION

For all of the reasons discussed above, the objections filed by the parties will be granted, denied, or reserved as listed in the chart included in the accompanying Order.

ALETA A. TRAUGER
United States District Judge